

## **TITLE 16. Board of Optometry**

NOTICE IS HEREBY GIVEN that the Board of Optometry is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at 400 R Street, Suite 4090, Sacramento, California, at 10:45 AM, November 19, 2003. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Optometry at its office not later than 5:00 p.m. on November 17, 2003 or must be received by the Board of Optometry at the hearing. The Board of Optometry, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by sections 3025, 3025.5, 3041, and 3041.2 of the Business and Professions Code, and to implement, interpret or make specific sections 3027.5, 3041, 3041.1, 3041.3, 3059, 3096.5, 3108, 3109, 3152.5, 4033, 4051 and 4052 of said Code, the Board of Optometry is considering changes to Division 15 of Title 16 of the California Code of Regulations as follows: Amendment of sections 1567, 1568 and 1569, Therapeutic Pharmaceutical Agents.

### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

1. Section 1567. This amendment will incorporate language in Business and Professions (B&P) Code section 3041 that adds therapeutic drugs (agents) to the list of pharmaceuticals optometrists are authorized to prescribe; define "treat" as applied to the usage of those agents; and define "approval" relative to Board authorization to perform lacrimal irrigation and dilation procedures on patients over twelve years of age.
2. Section 1568. This amendment will incorporate language in B&P Code section 3059 that requires optometrists who are certified to prescribe Therapeutic Pharmaceutical Agents to complete 35 of the required 50 hours of continuing education in diagnosis, treatment, and management of ocular disease. The proposed language also specifies the number of hours to be designated for training on particular conditions or diseases.
3. Section 1569. This amendment deletes previous conditions and optometrist/medical doctor protocols for peripheral infectious corneal ulcers and provides for the treatment of additional conditions, laboratory tests, the performance of new and further defined procedures. It also prohibits the use of injections except for auto-injectors to counter anaphylaxis and treatment of patients with AIDS.

## FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: none.

Business Impact:

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

### **AND**

The following studies/relevant data were relied upon in making the above determination: None.

Impact on Jobs/New Businesses:

The Board of Optometry has determined that this regulatory proposal will not have any significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business:

The Board of Optometry is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

## EFFECT ON SMALL BUSINESS

The Board of Optometry has determined that the proposed regulations would not affect small businesses because the amendments conform with statutory language that has already been implemented.

## CONSIDERATION OF ALTERNATIVES

The Board of Optometry must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

## INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Optometry has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

## TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Optometry at 400 R Street, Suite 4090, Sacramento, California 95814.

## AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

## CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Rex Farmer
Address:	400 R Street, Suite 4090 Sacramento, CA 95814
Telephone No.:	(916) 322-0961
Fax No.:	(916) 445-8711
E-Mail Address:	rex_farmer@dca.ca.gov

The backup contact person is:

Name: Jane Flint  
Address: 400 R Street, Suite 4090  
Sacramento, CA 95814  
Telephone No.: (916) 323-8720  
Fax No.: (916) 445-8711  
E-Mail Address: jane\_flint@dca.ca.gov

Website Access:

Materials regarding this proposal can be found at [www.optometry.ca.gov](http://www.optometry.ca.gov)

PROPOSED AMENDMENTS: CALIFORNIA CODE OF REGULATIONS  
SECTIONS 1567, 1568, and 1569

**Article 11. Therapeutic Pharmaceutical Agents**

**1567. Definitions.**

As used in this Article:

(a) "Infectious" means a type of lesion suspected to be caused by a pathogen.

(b) "NBEO" is the acronym for the National Board of Examiners in Optometry.

(c) "Peripheral Infectious Corneal Ulcers" means those infectious corneal ulcers limited to the area of the eye that lies outside the central 5mm diameter of the cornea.

(d) "Preceptorship service" means 65 hours of training in the diagnosis and treatment of ocular, systemic disease completed in no less than two months nor more than one year in one or more ophthalmologist's office(s) or optometric clinic(s). Preceptor's service shall be authorized by an accredited optometry school or college or recognized ophthalmological residency review committee in California. Preceptors shall be California-licensed ophthalmologists certified by the American Board of Medical Specialties and must be in good standing with the Medical Board of California.

(e) "Referral" means the primary responsibility for the treatment of a patient is transferred from the TPA optometrist to a consulting ophthalmologist.

(f) "Therapeutic Pharmaceutical Agents" includes mydriatics, cycloplegics, anesthetics, agents used for the reversal of mydriasis, topical lubricants, topical antiallergy agents, topical nonsteroidal antiallergy agents, topical nonsteroidal and steroidal ~~anti-inflammatories~~ antiinflammatories, topical antibiotic agents, topical hyperosmotics, topical antiglaucoma agents (use pursuant to the certification process defined in Business and Profession Code section 3041, subdivision (f)), oral antihistaminines, prescription oral nonsteroidal antiinflammatory agents, oral antibiotics limited to tetracyclines for treatment of blepharitis, dicloxacillin, amoxicillin, amoxicillin with clavulanate, erythromycin, clarythromycin, cephalixin, cephadroxil, cefaclor, trimethoprim with sulfamethoxazole, ciprofloxacin, and azithromycin (use limited to the eyelid infection and chlamydial disease, topical antiviral medication and oral acyclovir (use specified in Business and Profession Code section 3041, subdivision (c)(12), non-controlled substance oral analgesics, codeine with compounds and hydrcodone with compounds (use limited to three days) and topical miotics for diagnostic purposes and nonprescription medications.

(g) "TMOD" is the acronym for the "Treatment and Management of Ocular Disease" examination administered by the National Board of Examiners in Optometry. Passage of this examination is mandatory for certain TPA certification applicants.

(h) "TPA" is the acronym for Therapeutic Pharmaceutical Agents.

(i) "TPA certified optometrist" means a California licensed optometrist who has met all of the requirements for certification set forth by the State Board of Optometry to use Therapeutic Pharmaceutical Agents in his or her optometric practice.

(j) "Treat" means the use of therapeutic pharmaceutical agents, as described in Business and Professions Code section 3041, subdivision (c), and the procedures described in subdivision (e).

(k) "Approval" means to certify a TPA certified optometrist to perform lacrimal irrigation and dilation of patients over the age of 12 years pursuant to Business and Professions Code section 3041, subdivision (e)(6).

Note: Authority cited: Sections 3025, 3025.5, 3041, and 3041.2, Business and Professions Code. Reference: Sections 3027.5, 3041, 3041.1, 3041.3, 3059, 3096.5, 3108, 3109, 3152.5, 4033, 4051 and 4052, Business and Professions Code.

#### **1568. Therapeutic Pharmaceutical Agents Usage -Purpose and Requirements.**

Only those optometrists meeting the requirements of this Article may apply for TPA Certification to use Therapeutic Pharmaceutical Agents. The Application for TPA Certification (Form TPA-1 Rev. 4/96), which is hereby incorporated by reference, may be obtained from the Board's Headquarters office. Requirements for TPA certification are as follows:

(a) If the applicant is licensed to practice optometry in California and graduated from an accredited school of optometry prior to January 1, 1992:

(1) Completion of an 80-hour TPA didactic course provided either by the University of California at Berkeley School of Optometry or the Southern California College of Optometry or recognized ophthalmological residency review committee or at an accredited school or college located outside of California as provided in Section 1570 in this Article.

(2) Pass the examination given at the conclusion of the TPA course.

(3) Pass the TMOD component of the NBEO administered after July 1, 1992.

(4) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.

(5) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(b) If the applicant is a licensed optometrist in California and graduated from an accredited school of optometry after January 1, 1992 but before January 1, 1996:

(1) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.

(2) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(c) If the applicant is a graduate from an accredited school of optometry after January 1, 1996:

(1) Obtain a California optometrist license.

(2) Be certified by an accredited school of optometry that the applicant is competent in the diagnosis, treatment, and management of ocular, systemic disease.

(3) Be certified by an accredited school of optometry that the applicant has completed 10 hours of experience with an ophthalmologist.

(d) If the applicant is licensed outside California and graduated from an accredited school of optometry before January 1, 1992:

(1) Obtain a California optometrist license.

(2) Completion of an 80-hour TPA didactic course provided either by University of California at Berkeley School of Optometry or Southern California College of Optometry or recognized ophthalmological residency review committee or at an out-of-state school as provided in Section 1570 in this Article.

(3) Pass the examination given at the conclusion of the TPA course.

(4) Pass the TMOD component of the NBEO administered after July 1, 1992.

(5) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.

(6) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(e) If the applicant is licensed outside California and graduated from an accredited school of optometry after January 1, 1992 but prior to January 1, 1996:

(1) Obtain a California optometrist license.

(2) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.

(3) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(f) If the applicant is licensed in a state outside of California, graduated from an accredited school of optometry prior to January 1, 1992 and has practiced in that state, or on a reservation or a facility supported and maintained by the United States government with a TPA license:

(1) Obtain a California optometrist license.

(2) Pass the TMOD component of the NBEO administered after July 1, 1992.

(3) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(g) If the applicant is licensed in a state outside of California, graduated from an accredited school of optometry after January 1, 1992 but before January 1, 1996 and has practiced in that state or on a reservation or a facility supported and maintained by the United States government with a TPA license:

(1) Complete 20 hours of self directed study in the treatment and management of ocular, systemic disease.

(2) Complete a 65-hour preceptorship service as defined in Section 1567 in this Article.

(h) All TPA certified optometrists pursuant to this Article must complete 50 hours of continuing education in order to renew licensure. Thirty-five of the required hours shall be in the diagnosis, treatment and management of ocular, systemic disease **as follows: 12 hours on glaucoma, 10 hours on ocular infections;**

five hours on inflammation and topical steroids; six hours on systemic medications and two hours on the use of pain medications.

Note: Authority cited: Sections 3025, 3041, and 3041.2, Business and Professions Code. Reference: Sections 3027.5, 3041, 3041.3 and 3059, Business and Professions Code.

#### **1569. Scope of Practice.**

(a) Nothing in this section shall be construed to limit the scope of practice of an optometrist as it existed prior to the effective date of this regulation. Optometrists certified to use Therapeutic Pharmaceutical Agents (TPA certified) may also diagnose and treat the human eye or eyes, or any of its appendages, for all of the following conditions, exclusively:

~~(1) Allergies, infectious disease and non-systemic inflammations of the conjunctiva~~ Through medical treatment, infections of the anterior segment and adnexa, excluding the lacrimal gland, the lacrimal drainage system and the sclera. Nothing in this section shall authorize any optometrist to treat a person with AIDS for ocular infections.

~~(2) Eyelid margin inflammation and trichiasis, including blepharitis, Meibomian gland dysfunction and chalazia excluding cellulitis~~ Ocular allergies of the anterior segment and adnexa.

~~(3) Peripheral infectious corneal ulcers. This practice is limited to the initiation of treatment for ulcers which lie outside the central 5mm diameter of the cornea. The optometrist must communicate with and make a referral to a consulting ophthalmologist within 24 hours of the patient's first visit to the optometrist's office. Some sight threatening peripheral infectious corneal ulcers may require an immediate referral to an appropriate physician in less than 24 hours. This decision shall be at the optometrist's clinical discretion.~~

~~Treatment shall consist of the use of appropriate topical antibiotics. Cultures, smears or sensitivities may be appropriate depending on the clinical severity and/or clinical characteristics of the lesion. The optometrist shall keep records that, at a minimum, include a patient history, drawing(s) which show the general size and location of the lesion (photographs are acceptable as a substitute for drawings) and a description of the lesion.~~ Ocular inflammation, nonsurgical in cause, limited to inflammation resulting from traumatic iritis, peripheral corneal inflammatory keratitis, episcleritis, and unilateral nonrecurrent nongranulomatous idiopathic iritis in patients over the age of 18. Unilateral nongranulomatous idiopathic iritis recurring within one year of the initial occurrence shall be referred to an ophthalmologist. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of episcleritis within one year of the initial occurrence. An optometrist shall consult with an ophthalmologist if a patient has a recurrent case of peripheral corneal inflammatory keratitis within one year of the initial occurrence.

~~(4) Traumatic or recurrent conjunctival or corneal abrasions and erosion.~~

~~(5) Corneal surface disease and dry eyes.~~



(6) Traumatic or recurrent conjunctival or corneal abrasions and erosions.

(7) Ocular pain, not related to surgery, associated with conditions optometrists are authorized to treat.

(8) Pursuant to Business and Professions Code section 3041, subdivision (f), primary open angle glaucoma in patients over the age of 18.

(b) A TPA certified optometrist may also perform all of the following:

(1) Mechanical epilation

(2) Ordering of smears, cultures, and sensitivities, complete blood count, mycobacterial culture, acid fast stain, and urinalysis ~~used in the diagnosis of diseases listed above and within the scope of practice.~~

(3) ~~Use of punctal plugs that are diagnostic and absorbable and do not require punctal dilation~~ Punctal occlusion by plugs, excluding laser, cautery, diathermy, cryotherapy, or other means constituting surgery as defined in this chapter.

(4) Prescription of therapeutic contact lenses.

(5) Removal of superficial foreign bodies of the eyelid and conjunctiva.

(6) ~~Removal of corneal superficial foreign bodies above the Bowman's layer. If the foreign body is~~ of the cornea, eyelid, and conjunctiva. Corneal foreign bodies shall be nonperforating, be no deeper than the anterior stroma, and require no surgical repair upon removal. ~~within~~ Within the central 3mm of the cornea, the use of sharp instruments is prohibited.

(7) For patients over the age of 12 years, lacrimal irrigation and dilation, excluding probing of the nasal lacrimal tract. The State Board of Optometry shall certify an optometrist to perform this procedure after completing 10 of the procedures under the supervision of an ophthalmologist as confirmed by the ophthalmologist.

(8) No injections other than the use of an auto-injector to counter anaphylaxis.

(c) TPA certified optometrists are prohibited from treating children under one year of age with therapeutic pharmaceutical agents.

Note: Authority cited: Sections 3025, 3041, and 3041.2, Business and Professions Code. Reference: Sections 2266, 3027.5, 3041, 3041.1, 3108 and 3109, Business and Professions Code.